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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,787	08/16/1999	THOMAS EMRICH	BMID9913US	2784

23690 7590 10/27/2004

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/284,787	EMRICH ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *see attached*.

3. ☒ Applicant's reply has overcome the following rejection(s): see attached.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *18-25*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

ADVISORY ACTION

The amendment after final rejection filed on 9-13-2004 has not been entered. The proposed amendment raises new issues that would require further consideration and/or search.

Claims 18-25 are pending and currently under examination.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 20-25 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for reasons of record. Applicants arguments are predicated on an amendment not made of record and hence are deemed non-persuasive.

As outlined previously, it is apparent that mouse myeloma cell line P3x63-Ag8.653 is required in order to practice the invention as claimed (claims 20-21 and 23-25). The deposit of biological organisms is considered by the Examiner to be necessary for enablement of the current invention {see 37 CFR 1.808(a)}. Applicant has demonstrated that said cell line is publicly used. However, Applicant has failed to demonstrate that said cell ~~five~~ line was readily available to the public. Moreover, said availability must be for the life of any patent arising from the instant application.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless —
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 18-19 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hinds et al. (Journal of Medicinal Chemistry, 1991 Vol. 34, No. 6, pages 1777-1789 - IDS-6) is maintained for reasons of record.

The instant claims are drawn to monoclonal antibodies with a binding affinity of 10^8 to 10^{10} M^{-1} for the sequence YPYDVPDYA (SEQ ID NO:1) wherein said antibodies are drawn against a 13- or 14-amino acid containing epitope of human influenza virus haemagglutinin.

Applicants arguments are predicated on an amendment not made of record and hence are deemed non-persuasive. Consequently, the rejection is maintained for reasons of record.

35 USC § 103

Claims 18-21 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hinds et al. (Journal of Medicinal Chemistry, 1991 Vol. 34, No. 6, pages 1777-1789 - IDS-6) in view of Kuby (Immunology, Second Edition, W.H. Freeman and Company, 1994, pages 160-164).

Applicants arguments are predicated on an amendment not made of record and hence are deemed non-persuasive. Consequently, the rejection is maintained for reasons of record.

The instant invention is drawn to monoclonal antibodies with a binding affinity of 10^8 to 10^{10} M^{-1} for the sequence YPYDVPDYA (SEQ ID NO:1) wherein said antibodies are drawn against a 13- or 14-amino acid containing epitope of human influenza virus haemagglutinin and methods of making said monoclonal antibodies utilizing peptides comprising the sequence YPYDVPDYA (and derivatives thereof), rodents and a murine myeloma cell line.

As outlined previously, Hinds et al. disclose antibodies with a binding specificity to the sequence YPYDVPDYA (see abstract). Hinds et al. do not disclose the exact method steps recited in the instant claims. Specifically, Hinds et al. does not explicitly disclose the use of the P3-x63-AF8.653 murine myeloma cell line or the use of Lou/C rats. However, as disclosed by Kuby, the

methodology for producing monoclonal antibodies is well known in the art. An animal (rodent) is challenged with the antigen of interest. Spleen cells (source of primed B cells) are harvested from said animal and fused with HGPRT; IgG immortalized myeloma cells in polyethylene glycol. The resulting hybridomas are selected using HAT containing medium and screened for antibody production. Hybridomas producing the desired antibody are then subcloned. Since the production a given monoclonal antibody is predicated on the antigen used to immunize the animal, the selection of a specific animal and/or myeloma cell line merely constitutes a conventional alternative to the method disclosed by Kuby and hence would have been obvious to one of skill in the art.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 22 under 35 U.S.C. 112, second paragraph, as it is dependent on rejected claims is maintained.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman
October 25, 2004

L.F.S.
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